DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/04/2008 has been entered.

Status of Action

Receipt of Amendments/Remarks filed on 09/04/2008 is acknowledged. Claims 18-27, 29-34 are pending in this application. Claims 1-17, 28 have been cancelled; claim 18 has been amended; claims 19-27 are previously presented; claims 29-33 have been withdrawn; new claim 34 is added.

Receipt of Declarations of 37 CFR 1.131 and 1.132 filed on 09/04/2008 are acknowledged. However, the Declarations have not been considered because they identify a serial number other than the instantly claimed application. The declaration will be considered once the correction is made and resubmitted.

Status of Claims

Accordingly, claims 18-27, 34 are presented for examination on the merits for patentability as they read upon the elected subject matter and claims 29-33 directed to non-elected invention(s) are withdrawn.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejection(s) is/are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement of the Invention

Claims 18-27, 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 18-27, 34 while being enabling for treating an immune mediated disease selected from the group consisting of multiple sclerosis, rheumatoid arthritis, osteoarthritis, as claimed in claim 18, comprising the administration of a therapeutically effective amount of an estrogenic component of said formula, does not reasonably provide enablement for prophylactically treating

an immune mediated disease in aforementioned method due to the diverse origination and causes of said disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

An analysis of whether the scope of a particular claim(s) is actually supported by the disclosure in a patent application requires a determination of whether the disclosure, at the time of filing, contained sufficient information regarding the subject matter of the claim at issue so as to enable one skilled in the pertained art to use the claimed invention without undue experimentation. *In re Wands*, 8 USPQ 2d 140 (Fed. Cir. 1988). Therefore, the test of enablement is not whether experimentation is necessary, but rather, if experimentation is in fact necessary, whether it is reasonably considered to be undue. *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976). Determining the issue of enablement with respect to a claim is a question of law based on underlying factual findings. *In re Vaeck*, 20 USPQ 2d, 1444 (Fed. Cir. 1991). More particularly, there are many factors to be considered in determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and whether any necessary experimentation is reasonably considered to be "undue". See *In re Wands* at page 1404. MPEP § 2164.01(a). The court in *In re Wands* set forth the following factors to be considered, which included, without limitation, the: 1). scope or breadth of the claims; 2). nature of the invention; 3). relative level of skill possessed by one of ordinary skill in the art; 4). state of, or the amount of knowledge in, the prior art; 5). level or degree of predictability, or a lack thereof, in the art; 6). amount of guidance or direction provided by the inventor; 7). presence or absence of working examples; and 8).

quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Scope or breadth of the claims:

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, the prophylactically treating of immune mediated disorders which are developed from multiple origins and causes. However, Applicant is claiming utilizing one said estrogenic compound in said method can effectively treat an immune mediated disorder in a mammal, or can prophylactically treating said immune mediated disorder from occurrence, even though these diseases are very different in their multitude of development and their origination, implicitly include all causes and factors that give rise to such disorder can be treated or prophylactically treated by administering said single estrogenic compound.

Nature of the invention:

The nature of the invention is directed to a method of treating or prophylactically treating an immune mediated disorder in a mammal, such as multiple sclerosis, rheumatoid arthritis and osteoarthritis, by administering a therapeutically effective amount of an estrogenic compound to said mammal.

State of or the amount of knowledge in the prior art:

It is known in the art that the cause of multiple sclerosis is unknown and researchers are still not sure what triggers an attack to patients with multiple sclerosis except there appears to be

a genetic link to this disease (see MedlinePlus Medical Encyclopedia: Multiple Sclerosis, retrieved on 03/28/2008 via www.nlm.nih.gov/medlineplus/ency/article/000737.htm, dated on 08/06/2007, Page 1 and 2). It is also known that multiple sclerosis appears to affect woman more than man, and people with a family of multiple sclerosis and those who live in a geographical area with a higher incidence rate for multiple sclerosis have a higher risk of the disease (MedlinePlus Medical Encyclopedia: Multiple Sclerosis, retrieved on 03/28/2008, page 2; also see WebMD: Multiple Sclerosis – Prevention, retrieved on 03/28/2008 via www.webmd.com/multiple-sclerosis/tc/multiple-sclerosis-ms-prevention, dated on 03/23/2006).

In addition, the state of art(s) also recognize that, as of current, there is no known method to prophylactically treat rheumatoid arthritis because the exact cause of the disease is not known, and factors, such as infection, genes and hormones level, are speculated to contribute to this disease (see MedlinePlus Medical Encyclopedia: rheumatoid arthritis, retrieved on 03/28/2008 via www.nlm.nih.gov/medlineplus/ency/article/000431.htm, dated on 07/27/2007, page 1-2 and 4; also WebMD: Rheumatoid Arthritis – Prevention, retrieved on 03/28/2008 via www.webmd.com/rheumatoid-arthritis/tc/rheumatoid-arthritis-prevention, dated on 08/23/2006).

Therefore, currently there is no known method that can cure or can truly inhibit the immune mediated diseases, i.e. multiple sclerosis and rheumatoid arthritis, from occurrence by simply employing a single therapeutic estrogen because the causes of these diseases are still unknown and the occurrence of these diseases are derived from diverse factors.

Amount of guidance or direction provided by the inventor:

Although the instant specification discloses that said estrogenic component, such as estetrol, treats an immune mediated disorder, it remains silent on the prophylactic treatment of the immune mediated disorders, i.e. multiple sclerosis or rheumatoid arthritis, which may be caused by genetic or unknown promoting factors.

Presence or absence of working examples:

The specification provides some scientific data and working embodiments with respect to the administration of estetrol for treating multiple sclerosis and arthritis. However, in the specification, there is no example(s) of the administration of estetrol for prophylactically treating multiple sclerosis or arthritis as claimed in the instant invention.

Level or degree of predictability, or a lack thereof, in the art:

A high degree of unpredictability exists in the state of the art regarding how to inhibit the occurrence of multiple sclerosis or rheumatoid arthritis absolutely. Risk factors evaluation, although, may help to avoid the chances of further developing such immune mediated disorder, but at this stage of the art, many of them are still unknown and cannot be controlled, such as the factor due to the potential of weak immune system or the gene that one inherits from their parents.

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure:

One of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether said estrogenic compound and

corresponding method of the instant application does in fact effectively and prophylactically treat all the claimed immune mediated disorders in the instant invention.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the prophylactically treating an immune mediated disorder utilizing an estrogenic agent, is not enabled because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

It is noted to Applicants that claim 18 is drawn to method of treating or prophylactically treating an immune mediated disorder as recited therein. The Examiner takes the position that the term "prophylactically" means the same as "prevention", which is a preventive measure designed and used "to prevent a disease from occurring" (see Prophylactic definition - Medical Dictionary of Popular Medical Terms: retrieved on 03/14/2008 via www.medterms.com/script/main/art.asp?articlekey=11902). Since the term "prophylactic" is equivalent as "preventive"; therefore, instant claims 18-27, 34 are still construed to be directed to a method of "preventing" an immune mediated disorder in a mammal, and thus, they are rejected for the reason as set forth in the above.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/H. C./
Examiner, Art Unit 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616